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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,973	06/03/2002	Joaquin Andres Hoffer	22-62030	4373
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SEYFARTH SHAW 55 EAST MONROE STREET SUITE 4200 CHICAGO, IL 60603-5803			KRAMER, NICOLE R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/030,973	Applicant(s) HOFFER, JOAQUIN ANDRES	
	Examiner Nicole R. Kramer	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/24/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

2. The information disclosure statement filed 04/24/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the reference DE 4404842 has not been considered.

Claim Objections

3. Claim 18 is objected to because of the following informalities: The preamble states that the method is for providing an amputee with sensory feedback *from* a prosthetic limb. However, the final step of the method provides stimuli *to* the prosthetic limb and does not accomplish providing sensory stimuli from the prosthetic limb to the amputee's stump. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,314,495 ("Kovacs").

Kovacs discloses a microelectronic interface (200/250) comprising a plurality of electrodes (i.e., pairs of microelectrodes 22,24) placed in close proximity to a severed sensory nerve (352) in the limb stump (350) of an amputee. The microelectrode interface is used to localize stimulation or detection of action potential to a particular location on the nerve (see col. 6, line 12-14). When the microelectrode interface acts as a stimulator, it is supplied with electrical current from source 32 to provide electrical stimulation to the nerve. Kovacs discloses that a control processor may be used generate control signals to control each pair of microelectrodes for stimulation purposes (see Fig. 9 and associated text). Examiner considers "an electrical signal generator fashioned to communicated varying electrical signals to each electrode" to encompass

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such a control processor in that the control processor allows for stimulation of the microelectrodes in any arbitrarily selected pattern (see col. 12, lines 57-69). Examiner notes that "for alleviating phantom limb pain in an amputee" is a recitation of the intended use of the claimed invention, which must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The microelectrode interface of Kovacs is capable of alleviating limb pain in an amputee because it is capable of stimulating the severed nerve in the amputee's limb stump, and thus anticipates the system of claim 1.

6. Claims 1-3, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,824,027 ("Chen").

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. However, Examiner notes that applicant has admitted the nerve cuff of Chen to be prior art (page 14 of specification).

Chen discloses a plurality of electrodes (electrodes 34 are placed in plurality of chambers 30), with the electrodes necessarily placed in close proximity to a nerve passing through bore 25, said electrodes when supplied with electrical current provide electrical stimulation to the nerve. When the nerve cuff disclosed by Chen is used in nerve stimulation applications (see col. 8, lines 17-21), an electrical signal generator fashioned to communicate varying electrical signals to each electrode is necessarily present. Examiner notes that "for alleviating phantom limb pain in an amputee," and "implanted in said limb stump" are recitations of the intended use of the claimed invention, which must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The nerve cuff of Chen is capable of stimulating a severed sensory nerve in the amputee's limb stump, and thus anticipates the system of claim 1.

With respect to claim 2, the electrodes (34) are incorporated within a tubular nerve cuff fashioned to be implanted in the limb stump so as to circumferentially surround a portion of said nerve.

With respect to claim 3, the nerve cuff is multi-chambered (30), and the electrodes (34) are segregated into separate chambers of the nerve cuff.

7. Claims 1, 11, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,232,679 ("Schulman").

Schulman discloses a tissue stimulator comprising a plurality of electrodes (electrode pair A/B) located at tissue A/B, such as a nerve to be stimulated, which provide electrical stimulation to the nerve (see col. 4, lines 40-43; col. 14, lines 56-65). Schulman further discloses an electrical signal generator (pulse generator 14) that communicates varying electrical signals to each electrode (col. 4, lines 37-43). Examiner notes that "for alleviating phantom limb pain in an amputee," and "implanted in said limb stump" are recitations of the intended use of the claimed invention, which must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The implantable tissue stimulator of Schulman is capable of stimulating a severed sensory nerve in the amputee's limb stump, and thus anticipates the system of claim 1.

With respect to claim 11, the system of Schulman performs the method of claim 11 in that the system may be used to stimulate an amputee's severed nerve to alleviate phantom limb pain (col. 1, lines 32-40).

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8. Claims 1-10, 12-16, 18-19 are rejected under 35 U.S.C. 102(a) as being anticipated by "Strategies for providing upper extremity amputees with tactile and hand position feedback" (Riso).

Examiner has provided applicant a copy of Riso from Technology and Health Care (Fall 1999). However, Examiner has also provided applicant with citation that the same paper was previously published in "Proceedings of the International Biomechatronics Workshop" on April 1999, and therefore constitutes prior art under 35 U.S.C. 102(a).

Riso discloses a powered arm prosthesis with an integral system that provides cognitive sensory feedback of finger position and grasp forces via stimulation of the relevant afferent nerves within the residual limb (see Abstract and Fig. 4). The system comprises a plurality of sensors in the prosthetic limb, a microprocessor for signal encoding in the prosthetic limb, means for communicating the sensor signals to the stump (communicator in prosthesis/implanted receiver in stump), an implanted stimulator in the stump for communicating the electrical signals to electrodes in the microelectrode interface which is implanted on the sensory nerve (see Fig. 4). Riso discloses several embodiments of microelectrode nerve interfaces (see page 405), including a nerve cuff (embodiments a/b) that circumferentially surround a portion of the nerve. Examiner considers a "multi-chambered nerve cuff" to encompass embodiment (a) of Riso in that embodiment (a) includes a guidance chamber that circumferentially surround a portion of the nerve and a plurality of holes (chambers) each of which represent an addressable electrode contact.

With respect to claims 10 and 15, Riso discloses that one approach for sensory feedback is to use an intact sensory system such as a cutaneous sensation elsewhere on the body (i.e., a normally innervated limb) as an input channel for information related to the prosthesis (see Abstract).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,824,027 ("Chen"), as applied to claims 1-3 above.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference

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are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2). However, Examiner notes that applicant has admitted the nerve cuff of Chen to be prior art (page 14 of specification).

When the nerve cuff disclosed by Chen is used in nerve stimulation applications (see col. 8, lines 17-21), an electrical signal generator fashioned to communicate varying electrical signals to each electrode is necessarily present. However, Chen is silent as to the location of the electrical signal generator and the mode of communication between the nerve cuff and the electrical signal generator. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to place the signal generator outside the subject's body and communicate signals via telemetry to the nerve cuff because it is well known in the art that the electrical signal generator may be outside the subject's body, and the signals generated by the signal generator may be communicated telemetrically across the skin of the amputee.

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11. Claims 2-9, 12-14, and 17-18 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,314,495 ("Kovacs"), as applied to claim 1 above, in view of U.S. Patent No. 5,824,027 ("Chen").

As described above with reference to claim 1, Kovacs discloses a microelectronic interface (200/250) comprising a plurality of electrodes (i.e., pairs of microelectrodes 22,24) placed in close proximity to a severed sensory nerve (352) in the limb stump (350) of an amputee. With respect to claims 2 and 12, Kovacs fails to disclose that electrodes are incorporated within a multi-chambered tubular nerve cuff. Chen discloses a multi-chambered tubular nerve cuff that may be used to stimulate a severed nerve. It would have been obvious to one having ordinary skill in the art to modify the microelectronic interface of Kovacs to incorporate the electrodes in a multi-chambered tubular nerve cuff as taught by Kovacs because such a tubular configuration avoids the requirement that the electrodes are sutured to the nerve and allows the electrodes to be placed circumferentially around the nerve.

With respect to claims 4-7, Kovacs is silent as to where the control processor may be located. However, prosthesis 302 contains control circuitry (308/310) which controls the movement of the prosthesis and contains a transceiver 306 for communicating telemetrically with transceiver 304 implanted in stump 350. It would be obvious to one of ordinary skill in the art at the time of applicant's invention to locate the control processor in the prosthesis 302 since the prosthesis 302 contains algorithms and circuits that are already being implemented in a combination of hardware and software (col. 13, lines 50-65).

With respect to claims 8-9 and 12, Kovacs discloses that prosthetic limb 302 may contain sensors for tactile, position, and force sensing which are transmitted by transceiver 306 to transceiver 304 and through the microelectrode interface to nerve 352 to provide sensory feedback (see col. 15, lines 4-10). Although not explicitly stated, such sensory feedback is necessarily accomplished by utilizing the stimulation mode of the microelectrode interface. In the alternative, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to utilize the stimulation mode of the implanted microelectrode interface to stimulate the sensory nerve in order to provide the person with tactile, position, and force sensation and enhance the function of the prosthetic limb.

With respect to claims 13-14, non-electrical (i.e., telemetric) and electrical signal transmission are both well known in the art and recognized as equivalents. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to use either form of signal transmission because the selection of any of the art-recognized equivalents to transmit signals would be within the level of ordinary skill in the art.

With respect to claim 17, including a plurality of nerve cuffs for surrounding a different nerve would have been obvious to one having ordinary skill in the art at the time of applicant's invention, since it has been held that mere duplication of the essential working parts of a system involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

With respect to claim 18, the system of Kovacs/Chen would perform the method of claim 18, in that Kovacs discloses that the microelectrode interface provides sensed action potentials to the prosthetic limb 302 in order to control the movement thereof (see Fig. 10 and associated text) and that the sensors within the prosthetic limb 302 provide sensory feedback to the stump 305 (see col. 15, lines 4-10).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 3,955,560 teaches an implantable electrical unit which may transmit information to selected nerve fibers in the form of a stimulating electrical input.

"Afferent Sensory Feedback for Lower Extremity Prosthesis" (Clippinger et al.) teaches the use of direct afferent electrical stimulation to sensory nerves of an amputee to receive sensory feedback from a prosthesis. The system uses electrodes (2 x1 mm) randomly sutured onto the sciatic nerve.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

nrk

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7/19/05

George Manuel
George Manuel
Primary Examiner